Enhanced Security
the key to 21 CFR Part 11 technical compliance

WinLab32
UV WinLab ES
POL WinLab ES
Pyris ES
TotalChrom
LABWORKS ES LIMS
Spectrum ES
Spectrum Assure ID
We recognize the profound impact of the FDA’s 21 CFR Part 11 regulations on the operations of customers using our instruments and software. In response, we are pleased to introduce PerkinElmer’s Enhanced Security™ program — instrument and software solutions that enable you to achieve rapid technical compliance with the mandates of 21 CFR Part 11.

When a software program wears the Enhanced Security (ES) badge, it ensures the integrity of electronic data records that are generated under Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) protocols. The system provides technical compliance in terms of software development and data integrity, with extra security features that help create a secure, reliable environment.

Understanding that compliance is a multifaceted, ongoing process, we have designed our Enhanced Security program to extend well beyond software. We assembled a team charged with understanding these complex regulations and established a consistent approach to achieving technical compliance. Our software is developed and validated following a certified quality system which conforms to GLP, GMP and ISO 9001 guidelines.

Through our ongoing relationship with regulatory agencies around the world, we have developed an employee training program to ensure that software engineers and field sales and service personnel are knowledgeable about the regulations and their impact on PerkinElmer customers.

This brochure provides an overview of our Enhanced Security offerings to date, along with information on future compliance products and value-added services.

Take the first step toward compliance today. Call us toll-free at 800-762-4000 (+1) 203-925-4600 (Outside the US) or visit our Web site for more information about how your company can benefit from our Enhanced Security program.

Further Information: 21 CFR Part 11: A Primer For Analytical Labs (Literature number D-6661)
UV WinLab ES
integral compliance and high productivity
for UV/Vis analyses

Key Compliance Features
- Password protected access control
- Multilevel user permissions including access groups
- Login history including failed login detection and lockout
- Comprehensive audit trails for all security settings including users, groups and passwords
- Fully configurable electronic signature points, including method approval and results sign-off
- Electronic records stored in a secure database
- Legacy Data Tool — safe import via a security checksum

Technical compliance, including comprehensive audit trails and electronic signature points, is designed into the heart of the system, providing strict security (Fig. 1) and ensuring no compromise to laboratory throughput. All methods and results are stored in a secure, tamper-evident encrypted database that allows authorized users to manage and interpret results more efficiently.

Additionally, UV WinLab ES utilizes PerkinElmer’s new Communiqué™ reporting package, where the user can create customized, tamper-proof report templates (Fig. 2) using a simple drag and drop editor. The inclusion of import/export facilities along with company logos, results, sample descriptions and spectra allows for standardization of templates company-wide.

UV WinLab ES is available for the following UV/Vis spectrometers:
- Lambda 25/35/45
- Lambda 20/40 (Software upgrade only)

Operating System Support:
- Windows® 2000 and Windows XP

Further Information:
- UV WinLab ES Product Note (Literature number D-6696)
- Lambda Systems Brochure (Literature number D-6658)

From sample entry to reporting, UV WinLab™ ES provides a structured approach to running UV/Vis analyses that mimics the workflow of a busy laboratory. This minimizes operator training and increases productivity.

Lambda Series UV/VIS System

Fig. 1  Setting up account lockout criteria in UV WinLab.

Fig. 2  A Communiqué report template.
Spectrum ES software
security and simplicity for all FT-IR and FT-NIR analyses

**Spectrum ES Software**

**Key Compliance Features**
- Password protected access control including password aging and expiration (Fig 3.)
- Multilevel user permissions including access groups
- Login history including failed login detection and lockout
- Comprehensive audit trails for all security settings including users, groups and passwords
- Legacy Data Tool — safe import via a security checksum

Spectrum™ ES incorporates rigorous access control to ensure that valuable data cannot be deleted, overwritten or edited. To meet the requirement in 21 CFR Part 11 for authority checks, password-protection is linked to configurable user permissions to tailor the software to the training levels and responsibilities of individual users. Permissions and access groups are set by an administrator who can also configure the screen layout and menu structure to simplify analyses, reducing operator training and avoiding errors. Login history is fully audit trailed, including dates and times of successful and unsuccessful login attempts.

**Spectrum ES is available for the following FT-IR and FT-NIR spectrometers:**
- Spectrum One and Spectrum One NTS
- Spectrum GX and Spectrum GX Raman

**Operating System Support:**
- Windows 2000 and Windows XP

**Further Information:**
- Spectrum ES Product Note (Literature number D-6695)

Fig. 3 Administrator-definable password control in Spectrum ES.
Spectrum Assure ID software
FT-IR and FT-NIR materials identification and qualification systems

**Spectrum Assure ID**

**Key Compliance Features**
- Password protected access control
- Multilevel user permissions including access groups
- Login history including failed login detection and lockout
- Comprehensive audit trails for all security settings including users, groups, and passwords
- Configurable electronic signature points, including method approval and results sign-off
- Legacy Data Tool — safe import via a security checksum

Spectrum Assure ID™ builds on Spectrum ES to provide a complete FT-IR and FT-NIR materials identification system providing rapid confirmation of the suitability of, for example, incoming raw materials. By mimicking the QA workflow and using a powerful chemometric engine, AssureID enables users to develop, validate, and run methods, even if they do not have access to spectroscopists or chemometricians. Whether the AssureID system is a replacement for an existing method or part of a NDA, the time spent on method building and maintenance is dramatically reduced, maximizing return on investment and reducing testing costs. AssureID conforms to all regulatory requirements, including 21 CFR Part 11 (Fig. 4), and offers validation assistance tools to help speed up the validation process.

Data is stored in secure databases (Fig. 5). Full audit trails for administrative activities, method development history, instrument validation and results generation are easily accessible. Electronic signatures are supported when generating results as well as when approving methods and results.

**Spectrum Assure ID is available for the following FT-IR and FT-NIR spectrometers:**
- Spectrum One and Spectrum One NTS

**Operating System Support:**
- Windows 2000 and Windows XP

**Further Information:**
- Spectrum AssureID Product Note (Literature number D-6526)

Fig. 4 AssureID Group Permissions.

Fig. 5 Results trending using AssureID’s secures databases.
**Pyris ES** for thermal analysis compliance for sensitive data

**Key Compliance Features**
- User level management allowing configurable access permissions
- Login history including failed login detection and lockout
- File security and automatic versioning of files and data objects providing file integrity
- Comprehensive audit trails record all significant events and actions (Fig. 6)
- User-definable electronic signature points including customizable reasons.

Pyris™ ES ensures strict compliance with 21 CFR Part 11 for users of thermal analysis instrumentation in QA/QC and research functions. Rigorous user level management defines user groups and grants permission levels reflecting the laboratory workflow and the differing responsibilities of each user. Stringent password control ensures that only authorized individuals can access system functions, modify electronic records and sign off methods and results. Fully configurable electronic signatures can be defined throughout each analysis. The PerkinElmer Pyris Enhanced Security option is compatible with all instruments running on the Pyris software platform, allowing both new and existing customers access to the benefits of Enhanced Security.

Pyris ES is available for the following instruments:
- Diamond DSC, Pyris 6 DSC, Pyris 1 DSC, DSC 6, DSC 7
- Pyris 1 TGA, Pyris 6 TGA, TGA 6, TGA 7
- DMA 7e, TMA 7
- DTA 7
  (Requires Pyris TA Manager Software Version 5.0 or above)

**Operating System Support:**
- Windows 2000, Service Pack 2

**Further Information:**
- Pyris ES Product Note
  (Literature number D-6603)

Fig. 6 Audit trail records and displays all significant data and system changes.
PerkinElmer is the leader in inorganic analysis, with more than 40 years’ experience providing innovative, reliable solutions. WinLab32™ ES for AA (Atomic Absorption) and ICP (Inductively Coupled Plasma) redefines the software standard for inorganic analyses in highly regulated industries, where compliance with 21 CFR Part 11 is essential.

WinLab 32 ES combines powerful security features from Microsoft Windows 2000 and Windows XP with integral security features such as password-protected access and user groups with restricted permissions, each controlled by a system administrator (Fig. 7). This protects valuable methods and results, making sure that they cannot be overwritten, edited or deleted. Automatic version-control provides traceability, adding version numbers to all files and data sets and recording the changes between versions. Further security is provided by full audit trailing which records all system events, recording the user identity, permission status date, time and actions.

WinLab32 provides compliance for the industry’s leading AA and ICP solutions

**Key Compliance Features**
- Password protected access control
- Administrator-controlled group permissions
- Login history including failed login detection and lockout
- Automatic version-control of files and data sets
- Data security checksum
- Comprehensive audit trailing of all significant events and actions

WinLab32 ES is available for the following instruments:
- AAAnalyst™ 600/700/800
  (Note: WinLab32 Version 5.0 or higher for AA is required for the ES Software to be installed.)
- AAAnalyst™ 400
- Optima™ ICP-OES series
  (Note: WinLab32 Version 2.0 or higher for ICP is required for ES Software to be installed.)

**Operating System Support:**
- Windows 2000

**Further Information:**
- WinLab32 for AA and ICP: Enhanced Security Option (Literature number D-6596)

Fig. 7 WinLab32 for ICP User Setup utility.
TotalChrom
offers secure, complete solutions for chromatography data management

Key Compliance Features
- Fully compliant password protection
- Highly configurable access control with controlled group permissions
- Timestamped audit trails
- Electronic Signatures with configurable “reasons” lists
- Tamper-proof data integrity with tamper-evidence tracking

The scalable TotalChrom system maximizes productivity for demanding multi-user, multi-instrument installations, handling peak detection, integration and analysis for several instruments simultaneously. Data from several instruments can be viewed in real-time and are protected during acquisition even if clients, servers, or network peripherals are inoperative.

For rapid data analysis, report generation and distribution, the new TC Publisher tool is a state-of-the-art chromatography reporting package offering flexibility, speed and increased productivity.

TotalChrom is available for the following chromatographs:
- PerkinElmer Clarus Gas Chromatograph
- PerkinElmer Autosystem (XL) Gas Chromatograph
- PerkinElmer Series 200 Liquid Chromatograph
- Agilent HP1100 Liquid Chromatography
- Agilent 6890, 6890+ Gas Chromatograph
- Hewlett Packard 5890, 5890 Series II Gas Chromatograph

Operating System Support:
- Windows 2000
- Windows NT
- Windows 98

Further Information:
- TotalChrom Client/Server (D-6498)
- TotalChrom Workstation (D-6618)
- Achieving Compliance with TotalChrom Client/Server (D-6701)
LABWORKS ES LIMS
software for regulated laboratories

Key Compliance Features:
• Single, centralized point of authentication that controls access to all applications and data
• Access-control and authority checks to protect data
• Electronic signature points
• Data traceability tools
• IQ/OQ
• Validation Support

The new LABWORKS™ ES LIMS gives users the ability to develop more efficient data management processes and meet compliance requirements (Fig. 8). The new version also offers significantly reduced implementation time, low cost of ownership and minimal to no product customization before the LIMS goes live.

The new LIMS incorporates tools for managing electronic records and ensures traceability of data from time of entry through all subsequent business processes, establishing both a comprehensive event log and an audit history. Data is protected from accidental or intentional intervention by limiting access to authorized persons via a single, centralized point of authentication, which also allows implementation of electronic signatures.

A new Stability software module combines a browser-based user interface with state-of-the-art reporting capabilities and the speed and capacity of a true client/server application. The stability software assists in regulatory approval, minimizes training requirements and operator errors and ensures drug stability studies are managed efficiently.

Operating System Support:
• Windows NT, Windows 2000, Windows XP
Client

Further Information:
• D-6600 LABWORKS LIMS enterprise brochure

Fig. 8 User is prompted to verify identity after application inactivity timeout.
POL WinLab ES — compliance for polarimetry

**Key Compliance Features**

- Password protected access control
- Multilevel user permissions including access groups
- Login history including failed login detection and lockout
- Comprehensive audit trails for all security settings including users, groups and passwords
- Electronic signature points, including method approval and results sign-off
- Electronic records stored in a secure database

POL WinLab ES provides a thorough, compliant software platform for all polarimetry measurements, covering method development, routine testing, instrument control and validation and reporting. Access control restricts method building, editing and report template set-up to authorized users only, via password protection and group permissions, which are defined by an administrator (Fig. 9). For routine daily use, the analyst logs in to run simple, secure methods and report results. All activities are documented in comprehensive audit trails which also include electronic signatures for the approval of all methods, validation tests, results and reports.

**Operating System Support:**

- Windows 2000

**Further Information:**

- Series 341/343
- Polarimeters brochure
  (Literature number D-6328)

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Fig. 9 Method set-up and Instrument Status in POL WinLab.
value-added compliance services exceeding expectations

Uptime experts for your lab
Maximum productivity and optimum performance. How can you achieve it in your lab? Ask the uptime experts from PerkinElmer. We will assist you in improving every aspect of your lab’s performance, from instrument care and repair to education, validation, consulting and more.

Backed by leading-edge instrumentation experience, PerkinElmer’s uptime experts are passionate about exceeding customer expectation, every time.

We offer:
• More factory-trained service people than anyone else in the industry, available globally
• Expertise across a broad range of technologies
• Global processes that ensure consistent and reliable results

Validation
Today’s demanding regulatory environment makes proper validation increasingly important. Our experts offer a range of validation services to protect the integrity of your laboratory systems and ensure compliance with your organizations SOP’s as well as governmental and regulatory standards.

IQ/OQ Services:
PerkinElmer’s global team stands ready to make sure your instruments meet performance standards at the point of installation, through proven performance testing and documentation.

IPV Services:
In accordance with most Quality Systems and GLP guidelines, PerkinElmer can provide formal, precise and consistent verification and documentation every time your instrument is serviced or modified. Verification certificates and compliance stickers are provided onsite to indicate your IPV participation.

Instrument care and repair
Factory-trained experts ensure precise installation and meticulous maintenance of your analytical instruments and we offer preventative maintenance programs to help minimize cost of ownership. Our performance standards produce consistent results around the globe.

PerkinElmer offers:
• Extended Service Agreements
• Preventative Maintenance
• On-Demand Repairs
• Upgrades
• Instrument Relocation
• Global Parts Distribution Network

![Fig. 10 IQ/OQ Certification confirms all formal checks and documentation have been completed.](image-url)
PerkinElmer, Inc.

PerkinElmer, Inc. is a global technology leader focused in the following businesses — Life and Analytical Sciences, Optoelectronics, and Fluid Sciences. Combining operational excellence and technology expertise with an intimate understanding of its customers’ needs, PerkinElmer creates innovative solutions that accelerate drug discovery, enhance research productivity, help meet regulatory requirements, improve time-to-market and increase manufacturing efficiencies.

There are over 60 years of experience built into every product we make, backed by an unparalleled service and support team that serves customers in more than 125 countries around the world. And online consumables, reagents and accessories ordering lets you get your hands on what you need fast.

Additional information on the company is available through www.perkinelmer.com or 1-877-PKI-NYSE.